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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.. |
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| 09/655,336 | 09/05/2000 | Tomoko Ueda | 1422-437P | 9668 |

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/02/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/655,336

Applicant(s)

UEDA ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 9,10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,11,16-18 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Request for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/655336 filed on August 16, 2001 is acceptable and a RCE has been established. An action on the RCE follows

Applicants' election in the parent application is presumed to carry over to the instant RCE since applicants have not indicated a contrary intention. Applicants elected "premenstrual syndrome" as elected species in paper No. 6. Claims 9, 10, 12-15 are withdrawn from further consideration as drawn to non-elected species.

Claim Objection

1. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim recites theanine as theanine extract. Theanine extract is not isolated theanine.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. The term "crudely" in claim 24 is a relative term, which renders the claim indefinite. The term "crudely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The claim is indefinite as to the purity of the theanine. The argument that "the crude isolation of plant extracts is well known in the art" is not probative.

Claim Rejections 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by applicants' own admission

6. The specification on page 4, line 25 bridging page 5, line 4 disclose that theanine is a known major component in tea and is known to be used as food additive. The instant claims are drawn to a method comprising administering to women with PMS a composition comprising theanine. The composition herein read on tea and any other food containing theanine. Drinking tea has been a common and well-known practice in this country. The people who drink tea are reasonably expected to including at least some of the women with PMS. It is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior

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art, does not cause a claim drawn to those things to distinguish over the prior art.” Claim 24 is properly rejected because tea is a theanine extract. Further note, there is not limitation about the amount of L-theanine required in the method.

Claim Rejections 35 U.S.C. 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8, 11, 16-18 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji et al. (JP 406100442) in view of Merck Manual (fifteenth edition) and applicant .

9. Fuji et al. teaches a anti-stress composition comprising L-theanine as the active ingredient and, optionally, other nutritional ingredients, including minerals, e.g., magnesium.

The composition is safe and with no particular limitation in its usage. The composition may in various form, including tablet, drink etc. a tablet may contains 200 mg of L-theanine; drink may containing 1 gram of L-theanine per liter. See, particularly, the abstract, the examples 2-4 in column 4-5 and the example in column 6.

10. Fuji et al. does not expressly teaches to employ the composition for treating premenstrual syndromes. However, as shown in Merck Manual, it is well known that the most common complaints of PMS are mood alteration and psychological effects: including irritability,

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nervousness, depression etc, and stress reduction is one of the known treatment of PMS in the art. See, Merck Manual, page 1711.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the anti-stress composition of Fuji et al. for treating PMS.

A person of ordinary skill in the art would have been motivated to employ the anti-stress composition of Fuji et al. for treating PMS because stress reduction is a well-known method for treating PMS and because the safety of the composition. (no side effect).

Response to the Arguments

Applicants' arguments submitted March 19, 2002 have been fully considered, they are mostly moot in view of above rejection, and are not persuasive with respect to the rejection under 35 U.S.C. 112 and 102 herein for reasons discussed below.

Applicants' assertion that "crude isolation of plant is well known in the art" is not persuasive because there is no factual base to support the assertion. Further, as stated in the rejection under 102, the limitation of "crudely isolated theanine/or theanine extract" arguably read on tea, which is a extract containing theanine. Absent clear definition of "crudely" in the specification, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As broadly read, the claim is also properly rejected under 35 U.S.C. 102 for reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to read 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

June 28, 2002